



Study Status

Study AC-060A202: CONTROL
Roland Reuling



Study Overview

- Number of countries 13
- Number of sites 99
- Number of patients 13/412
- First site initiation: 1 November 2010
- First patient randomized: 17 November 2010
- Recruitment period: 1 year
- LPLV: 15 Mar. 2012
- Database Lock: 27 Apr. 2012
- Investigator Meetings: 7-8 Oct. 2010 (Sydney), 19-20 Oct. 2010 (Prague), 29-30 Oct. 2010 (Chicago), 14-15 Jan. 2011 (Miami), 20-21 Jan. 2011 (Barcelona) and 9-10 Feb. 2011 (Durban)

Site Selection Overview

Country	Total sites selected	PK-CM substudy Total sites selected
Australia	3	
Bulgaria	4	2
Germany	8	3
Hungary	9	3
Israel	7	2
Poland	5	3
Russia	10	5
Serbia	2	1
Singapore	1	
South Africa	9	4
Sweden	7	7
Ukraine	10	7
United States	24	6
TOTAL	99	43

Investigator Meeting Barcelona: participating sites

Country	PI Name
Bulgaria	Dimitrov
Bulgaria	Dimov
Bulgaria	Metev
Bulgaria	Georgiev
Poland	Buczylko
Poland	Emeryk
Poland	Majorek-Olechowska
Poland	Pulka
Poland	Siergiejko
Russia	Chuchalin
Russia	Fassakhov
Russia	Kuzubova
Russia	Komlev
Russia	Martynenko
Russia	Popova
Russia	Bukreeva
Russia	Nasenkova
Russia	Reutskaya
Russia	Sinopalnikov

Country	PI Name
Serbia	Čeleketić
Serbia	Vukcevic
Sweden	Nilsson
Sweden	Björkander
Sweden	Kempe
Ukraine	Blazhko
Ukraine	Feshchenko
Ukraine	Yashyna
Ukraine	Monogarova
Ukraine	Kraydashenko
Ukraine	Vizir
Ukraine	Chohey
Ukraine	Boyko
Ukraine	Godlevska
Ukraine	Smolyanyi
Total	34

PK-CM sub-study sites

Site number	Country	Investigator Name
5101	Bulgaria	Dimitrov
5103	Bulgaria	Metev
5503	Poland	Majorek-Olechowska
5505	Poland	Pulka
5507	Poland	Siergiejko
5603	Russia	Fassakhov
5604	Russia	Kuzubova
5605	Russia	Komlev
5606	Russia	Martynenko
5654	Russia	Sinopalnikov
5701	Serbia	Čeleketić
6004	Sweden	Nilsson
6005	Sweden	Björkander
6006	Sweden	Kempe
6101	Ukraine	Blazhko
6102	Ukraine	Feshchenko
6103	Ukraine	Iashyna
6104	Ukraine	Monogarova
6105	Ukraine	Chohey
6106	Ukraine	Vizir
6107	Ukraine	Kraydashenko
Total		21

HA/EC: Countries approved

HA approvals obtained

- Australia, Germany, Hungary, Israel, Singapore, South-Africa, Sweden, USA

EC approvals obtained

- Australia, Germany, Hungary, Poland, Russia, Serbia, Singapore, South-Africa, Sweden, USA

Vendors

- ACM: Central Lab
- ERT: ECG and Holter Monitoring (Sub-study only)
- ICON: IVRS/IWRS
- nSpire: Spirometry, e-Diary and e-Peak Flow Meter



Global Study Team



HQ Allschwil, Switzerland

- Dorothea Scholl – Global Trial Leader
- Miyuki Tomioka – Clinical Research Scientist
- Nives Selak Bienz – Clinical Research Scientist
- Stefan Hellbardt – Science Project Leader
- Sara Mangialaio – Science Project Physician
- Hans Hoogkamer – Life Cycle Leader
- Roland Reuling – Clinical Trial Project Manager
- Uwe Althausen – Clinical Trial Operations Manager
- Marco Nief – Clinical Trial Operations Manager
- Laura Alberti – Clinical Trial Operations Manager
- Camilla Nicolet – Clinical Trial Assistant
- Raymonde Kleiber – Clinical Trial Documentation Specialist
- Reilinde Nopper – Clinical Operations Product Leader
- Aurélien Thiers – Senior Data Manager

Country Study Team



Bulgaria

- Violeta Zaharieva, Monitor



Hungary

- Agnieszka Lyczba, ROM
- Gergely Csuz, Monitor



Serbia

- Marko Borisavljevic, Monitor



Poland

- Lukasz Sobiak, ROM
- Agnieszka Kwiatkowska, Monitor



Russia

- Nina Cherkasova, ROM
- Irina Suvorova (PSI), Project Manager
- Alexey Gilfanov (PSI), Monitor
- Dmitry Bulantsev (PSI), Monitor



Ukraine

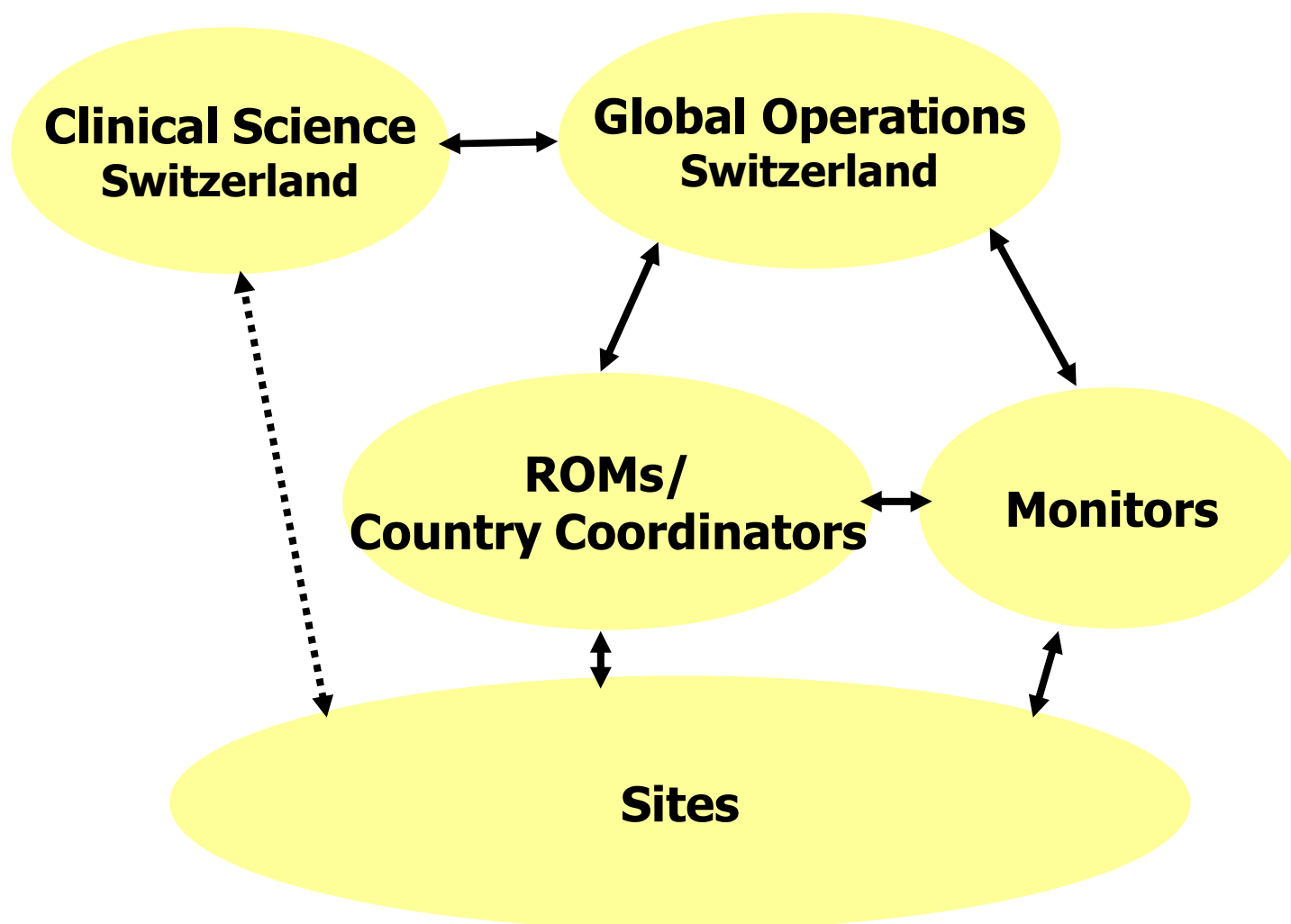
- Natalya Smiyan (PSI), Monitor
- Olga Gromova (PSI), Monitor



Sweden

- Maria Wahlström, ROM
- Lena Barret, Monitor

Communication Flow





Thank You!

